Kraft Foods

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Stuart Shapiro
FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th St., N.W.
Room 10235
Washington, D.C. 20503

Re: Prior Notice of Imported Food
Docket No. 02N-278; RIN 0910-AC41

Dear Mr. Shapiro:

Kraft Foods is a $30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. We have plants located just over both the Canadian and Mexican borders. We import roughly 200 ingredients from almost 100 countries. We also sell in the US products made in our facilities around the world. Thus, we have a substantial interest in the rules governing the importation of food products, which are now being developed by the Food and Drug Administration (FDA).

Kraft commends the FDA personnel who are working to implement the Bioterrorism Act so quickly. We understand the pressure under which the agency's officials have been operating and the long hours they have invested. We appreciate their service. We also share the government's goal of protecting the food supply, since our products are found in 99.6% of American households and are sold in 150 countries around the world.

While we have carefully evaluated the proposed rules, we are not yet confident that we understand the myriad logistical implications of the new information gathering requirements, especially for trade across the Canadian and Mexican borders. In these comments, we highlight the most significant issues we have identified, attempting to suggest solutions in addition to pointing out problems. From afar we cannot appreciate all the systems constraints imposed on FDA, so solutions that seem straightforward to us admittedly may be less viable in a non-industry setting than we anticipate. Nevertheless, if FDA were to adopt the rules as proposed, confusion--even gridlock--at

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US borders would be inevitable in December, so changes must be made to avert that outcome.

To Kraft, the most troublesome aspect of the FDA prior notice proposal is that the agency is not planning to integrate the new information collection system with the existing system--or with existing Customs Service systems. Instead of moving forward the time FDA receives entry information from the Customs/FDA OASIS system, the agency proposes to establish a second entirely separate "prior notice" data collection system. Under the FDA proposal, an importer would have to feed data to the new prior notice system, but also still would have to continue to send data independently to the existing Customs/FDA OASIS system, and incidentally pass through two potential inspection points rather than one.

We are concerned not only about proposed information requirements that duplicate those in the existing systems, but also about the implications of disrupting essential systems links that now exist, such as between the FDA and Customs systems. In particular, we will be participating in the Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free And Secure Trade (FAST) programs, both of which expedite processing of shipments, especially intra-company shipments, for low risk importers like Kraft. We are aware that Customs is in the process of adopting additional prior notice and entry requirements, in addition to those being adopted by FDA. Erecting an unduly high wall of electronic paperwork at the border would substantially impede legitimate trade, and we question whether security would be materially improved.

The new Customs Automated Commercial Environment (ACE), which ideally will address systems integration and duplication of data issues, is not scheduled to be fully implemented for several years. Meanwhile, to reduce duplicative data entry, FDA should try to find a way to forward the data entered into the prior notice system to the Customs/OASIS system. If systems constraints prevent such data transfer, we recommend that FDA refrain from adopting information gathering requirements that significantly exceed those set forth in the Bioterrorism Act, at least until adequate systems support becomes available.

The burden on trade would be reduced significantly, if FDA were to adopt a constant number of hours as a required notice period, instead of the proposed notice deadline of noon on the calendar day before arrival. With a rolling notice period, supply chain labor could be spread throughout the day, rather than peaking with accelerated demand as people try to avoid the penalty imposed by missing the noon deadline. Furthermore, the proposed notice period is so long that the number of required amendments to identity information and updates to arrival information will drain both FDA and industry

resources. A rolling notice period of 4 to 8 hours, not tied to a calendar day, would drastically reduce the need for repetitive submissions associated with the same entry.

Our more detailed comments are provided below in answer to the key questions that Office of Management and Budget (OMB) will be examining as required by the Paperwork Reduction Act.

Is the information necessary and will it have practical utility?

For each prior notice of entry, FDA proposes to collect much more information than is required by the Bioterrorism Act, without explaining why the information is needed for day to day entry screening. The information items in the proposed rule are listed below, with those required by Congress shown ***in bold type***. All of the other information items were added by FDA, apparently in an effort to compile a comprehensive list of information that potentially might be of interest.

- Submitter
  - individual, firm
  - address, email address
  - phone, FAX
  - registration number
- Customs entry type
- ACS entry number
- Hold information
- ***Growers, if known***
- ***Originating country***
- ***Shipping country***
- Anticipated arrival
  - ***port of entry***
  - date & time
- ***Article Identity***
  - FDA product code
  - common name
  - trade or brand name
  - quantity (smallest package size to largest container)
  - lot, code, identifying numbers
- ***Manufacturer***
  - address, email address
  - phone, FAX
  - registration number

- ***Shipper***
  - address, email address
  - phone, FAX
  - registration number
- Customs port of entry
- Customs date of entry
- All carriers
  - names
  - address, email address
  - phone, FAX numbers
  - Standard Carrier Abbreviation Codes (SCAC)
- Importer
  - address, email address
  - phone, FAX
  - registration number
- Owner
  - address, email address
  - phone, FAX
  - registration number
- Consignee
  - address, email address
  - phone, FAX
  - registration number

The need for gathering some data beyond the minimum required by law, such as the manufacturer's registration number, is easily understood. Not so readily apparent is the need for predicting less relevant and less certain information, like the Customs date of entry, which as FDA recognizes may be several days after the prior notice is filed. To justify collecting such additional information, the agency should explain, at least to OMB, how the data will be used in the various day to day entry screening algorithms that will be programmed into the agency's computer system.

With regard to the practical utility of the new information, much of the information FDA proposes to gather already is collected through the existing Customs and FDA OASIS systems. In fact, FDA acknowledges, "Most of this information is already supplied by the filer to FDA through ACS as part of the U.S. Customs entry process....." 68 Fed. Reg. 5435. Therefore, we have difficulty understanding why FDA could not just move forward the time for submitting the currently required information, so that the new prior notice of entry system would replace the existing system for screening imports. There must be some way to avoid the use of two duplicative systems that are costly and inefficient for both FDA and industry.

Is the agency's estimate of the burden of collecting the information accurate? Are the assumptions used valid?

FDA quite correctly acknowledges that "a four hour minimum prior notice requirement would be less likely to change current food importing practices than would a longer minimum time requirement for prior notice submission." 68 Fed. Reg. 5443. The agency also accurately recognizes that many foods are sourced close to the US border, making the four hour notice requirement most consistent with current business systems. *Id.*

The agency's analysis derails when FDA proceeds to conclude, at least tentatively, that the information required in the prior notice would be fixed at the time an order is placed, which we know usually is the not case for the shipments we import. Our plants ordinarily make products according to a plan that is based upon a forecast, not in response to individual orders. The exact quantities available for shipment sometimes depend upon factors like whether a machine malfunctions, packaging is delivered late, or personnel call in sick on a particular day.

Even when most of the information required for the prior notice is known at least by the day before shipment, the exact identity of all carriers and the time of arrival at the border often are not yet known. Estimating the time of arrival at US Customs from Mexico is especially challenging. The Mexican carrier must first arrive at the Mexican Customs broker for administration of the paperwork, then must clear Mexican Customs. Mexican carriers currently cannot complete a delivery to our warehouses in the US. Therefore, the Mexican carrier stops to do a mechanical inspection of the trailer and then transfers the trailer to a drayman carrier. The draymen carrier takes the shipment across the bridge to US Customs. Delays may occur at any of these checkpoints, making arrival time difficult to predict accurately.

Today, two streams of information flow separately from the shipper, one to the US broker and another to the carrier. North American carriers usually do not contact the broker until the truck arrives at the US border. The level of detail FDA proposes to require will force significant changes in business systems to bring the two separate steams of information together in time to meet whatever prior notice requirement FDA adopts. The last piece of available information, which may be the quantity, carriers, or time of arrival, will drive the shipper's ability to comply with the notice requirements. Thus, the more flexible the agency's processes for amending and updating data, the more readily industry will be able to comply with the prior notice requirement.

According to the agency's analysis of economic impacts, noon the calendar day before arrival (option five) turned out to be the most cost effective prior notice option, but FDA allowed amendments and updates until two hours before arrival only for that option, not for any of the other options considered. If the same assumptions about amendments and updates had been incorporated into the analysis of the other options, the four hour advance notice option (option two) would have been the most cost effective.

In fact, careful examination of Table 17 and the accompanying text shows that the agency's economic analysis is driven entirely by assumptions about timing of acceptable amendments and updates. 68 Fed. Reg. 5453. For example, in evaluating the four hour notice option, FDA assumed that 20% of all entries would need to be resubmitted, resulting in at least another four hour delay and consequent loss of value for perishable items. 68 Fed. Reg. 5443. In contrast, FDA estimated that only 5% of entries would need to be resubmitted in the noon of the calendar day before entry option, due to the amendment and update provisions. Consequently, the agency reduced the assumed loss in value of perishable goods accordingly. Yet, if the same amendment and update possibilities had been allowed in all the different scenarios being evaluated, the shortest notice period would have been identified as the lowest cost option. Actually, the four hour notice period would require far fewer amendments and updates than would the day before entry notice requirement, since the data submitted to FDA would be more certain, further reducing overall cost and improving efficiency.

In the analysis of economic impacts, FDA considered the cost of delayed shipments only for shipments of highly perishable foods. The cost of delay is quite real for all food products and delayed shipments also incur additional transportation charges. Both of these costs should be recognized as the agency considers the prior notice period requirements. The shorter the notice period, the lower the cost of delayed shipments.

Moreover, the FDA analysis entirely omits the costs of changing business systems used by processors, brokers, and carriers. Not only must programming changes be made to accommodate the new requirements, contracts and pricing must be renegotiated. Additionally, personnel throughout the entire supply chain must be trained to comply with the new rules.

On the benefit side of the analysis, FDA uses domestic food borne illness outbreaks as a rough measure of benefit related to increased import inspection, although only one of the outbreaks cited was associated with imported food. All the domestic food borne illnesses outbreaks were caused by invisible agents that could not be detected by a border inspector. Thus, offsetting the cost of the prior notice system with presumed reduction in overall food borne illness seems at best questionable.

How could the quality, utility, and clarity of the information be enhanced?

FDA could reduce the rate of errors as the new system is introduced by clarifying the agency's expectations in several respects. First, with regard to product identity, FDA should explain in the preamble to the final rule that as long as the basic nature of the food is properly identified on the prior notice, the amendment process may be used for minor changes to product variety, flavor, or size . For example, if a piece of manufacturing equipment breaks down or a different type of truck arrives, adjustments would be allowed as long as an amendment is filed in the following situations:

1. the mix of different flavors of Jell-O gelatin dessert on a truck could be adjusted;
2. the quantities of macaroni and cheese dinners in different size boxes or with different noodle shapes could be adjusted;
3. different varieties of ready to eat pudding could be used to "top off" a truck.

Identity amendments should be limited only when the fundamental nature of the product changes. For example, pudding could not be used to "top off" a truck of macaroni and cheese dinners. Allowing reasonable amendments would improve the agency's resource allocation as well as industry's.

Many products carry several brand names. For example, an OSCAR MAYER LUNCHABLE lunch combination could be made with KRAFT cheese, TOMBSTONE pizza sauce or RITZ crackers, NABISCO OREO or CHIPS AHOY cookies, and a CAPRI SUN juice drink. The brokers who will be completing the prior notice typically are not familiar with the fine distinctions between the various types of common names and brand names on a label. Indeed, we have encountered both FDA inspectors and our own internal personnel who find this area of law confusing. Brand name manufacturers should not be required to assume greater risk that the broker will complete the data screen incorrectly than generic manufacturers. Should it ever become necessary, the manufacturer or importer can identify brand names.

There has been some confusion throughout the industry concerning whether FDA plans to allow quantities and lot numbers to be adjusted through amendments, although to us it seems clear that the regulation does and should permit such adjustments. Perhaps the confusion is coming from the proposed form, which has a box for indicating a change to product identity. Under the regulation product identity includes quantity and lot number, but the technical elements of product identity may not be readily apparent to everyone who must complete the data screen. Thus, we recommend clarification of the agency's expectations.

Furthermore, the value of requiring "lot, code or other identifying number" at all is unclear. Many products have code and lot numbers, but not all do. The proposed requirement for "other identifying number" seems so vague that it would be difficult to enforce and hardly provide useful information. FDA should consider dropping this requirement. If the requirement remains, FDA should clarify the agency's expectations.

FDA should explain how the agency proposes to determine arrival time, especially when there are lines at the border. The arrival time window FDA proposes is quite narrow: one hour early or three hours late. FDA should provide notice of how the agency plans to regulate compliance during busy periods, when a truck could wait in line long before reaching the US Customs official.

Furthermore the mechanics of filing amendments and updates are unclear. The proposed form needs to be reworked in response the comments OMB and FDA are now receiving, especially from the various trade associations.

What could be done to minimize the burden of the collection of information on those who are to respond?

If FDA adopted a rolling 4 hour or 8 hour prior notice period, not tied to a calendar day, the burden associated with the notice requirement would be reduced significantly. By tying the notice to noon of the calendar day before arrival, the agency's proposal, in effect, would establish a notice requirement of just over 12 hours for entries processed in the morning, but a requirement of over 36 hours for entries processed during the afternoon. This disparity would cause shippers, brokers, and carriers to try to avoid the 24 hour "afternoon" penalty, distorting allocation of resources throughout the supply chain and creating a logistical nightmare. Additionally, with a shorter prior notice period, the information collected by FDA would be less likely to change, reducing the number of required amendments and updates that must be processed and evaluated for each entry.

The requirement to amend identity information, including precise quantity information, at least 2 hours prior to entry easily could be replaced with a requirement to amend the data by the time of entry, without compromising security. Eighty percent of our Canadian plants are located less then two hours from the border. While approximate quantities ordinarily would be known the day before a shipment, the exact quantities on a truck often are not known until the truck is sealed and ready to leave for the border. As only minor adjustments to identity and quantity are allowed through the amendment process, giving shippers more time to file accurate information ultimately would reduce

the FDA resources devoted to immaterial paperwork changes. Approximate quantity information certainly should be accurate enough for the agency's inspection decisions.

Similarly, making the rules on updating estimated arrival time more flexible would reduce unnecessary cost associated with the new system. For example, FDA could drop the requirement for updating arrival time 2 hours before entry, if the truck might arrive one hour earlier than anticipated. A requirement to notify FDA at least one hour before reaching the border would be more workable. Instead of requiring updates to arrival time if the truck is more than three hours late, the agency could require an update only if the truck will be more than eight or more hours late, significantly reducing the unimportant data FDA is expected to process. FDA inspectors do not need to be present when the truck arrives at the border; the agency only needs to notify Customs, if a truck must be detained. Therefore, establishing too tight a window for arrival time is unnecessarily costly and an eight hour window is consistent with common practice in industry.

Conclusion

If government and industry together are to assure the safety of the food supply, without at the same time imposing unnecessary costs on American citizens, deploying resources as effectively and efficiently as possible is critical. Adjusting the information collection requirements for food imports as we have suggested will enable FDA and industry to comply with Congressional directives without wasting or misdirecting resources that could be better used for more focused security measures.

Kraft always stands ready to work with the government to protect the safety of the food supply. Please do not hesitate to contact me at (847) 646-6125, if we can provide additional information that might be helpful.

Sincerely,

Jean E. Spence

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Senior Vice President
Worldwide Quality, Scientific Affairs and Compliance

cc: FDA Docket 02N-0278